

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

CADENCE PHARMACEUTICALS, INC.
and SCR PHARMATOP,

Plaintiffs,

v.

PADDOCK LABORATORIES, INC.;
PERRIGO COMPANY; and PADDOCK
LABORATORIES, LLC;

Defendants.

Case No.

11-2399 SRN/TM

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MINNEAPOLIS, MN.

COMPLAINT

Plaintiffs Cadence Pharmaceuticals, Inc. and SCR Pharmatop (collectively, “Plaintiffs”) for their Complaint against defendants Paddock Laboratories, Inc.; Perrigo Company; and Paddock Laboratories, LLC (collectively, the “Paddock Defendants”), allege as follows:

PARTIES

1. Plaintiff Cadence Pharmaceuticals, Inc. (“Cadence”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 12481 High Bluff Drive, Suite 200, San Diego, California, 92130.

2. Plaintiff SCR Pharmatop (“Pharmatop”) is a civil law partnership organized and existing under the laws of France, having its headquarters at 10, Square St. Florentin, 78150 Le Chesnay, France.



3. Upon information and belief, defendant Paddock Laboratories, Inc. (“Paddock”) is a corporation organized and existing under the laws of the State of Minnesota, with headquarters at 3940 Quebec Avenue North, Minneapolis, MN 55427. Upon information and belief, Paddock is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district.

4. Upon information and belief, defendant Perrigo Company is a Michigan corporation, having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Upon information and belief, Perrigo Company acquired substantially all of the assets of Paddock on or about July 26, 2011. Upon information and belief, Perrigo Company is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district.

5. Upon information and belief, defendant Paddock Laboratories, LLC (“Paddock LLC,” and collectively with Perrigo Company, “Perrigo”) is a Delaware corporation, having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Upon information and belief, Paddock LLC is a subsidiary of Perrigo Company organized to integrate Paddock’s business portfolio with Perrigo Company’s business portfolio. Upon information and belief, Paddock LLC is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district.

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent No. 6,028,222 and U.S. Patent No. 6,992,218 (collectively, the “Patents-in-Suit”). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Paddock by virtue of, *inter alia*, Paddock’s incorporation, continuous presence and principal place of business in the State of Minnesota.

9. This Court has personal jurisdiction over Perrigo Company because, *inter alia*, Perrigo Company has purposefully availed itself of the rights and benefits of Minnesota law by engaging in systematic and continuous contacts with Minnesota.

10. Upon information and belief, defendant Perrigo Company regularly and continuously transacts business within the state of Minnesota, including by selling pharmaceutical products in Minnesota. Upon information and belief, Perrigo Company derives substantial revenue from the sale of those products in Minnesota and has availed itself of the privilege of conducting business within the State of Minnesota.

11. This Court has personal jurisdiction over Paddock LLC because, *inter alia*, Paddock LLC has purposefully availed itself of the rights and benefits of Minnesota law by engaging in systematic and continuous contacts with Minnesota.

12. Upon information and belief, Paddock LLC regularly and continuously

transacts business within the state of Minnesota by integrating Paddock's business portfolio with Perrigo Company's business portfolio and further by manufacturing, distributing, and selling pharmaceutical products in this judicial district.

13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b).

THE PATENTS-IN-SUIT

14. United States Patent No. 6,028,222 ("the '222 patent"), titled "Stable Liquid Paracetamol Compositions, and Method for Preparing the Same," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on February 22, 2000, to Pharmatop, the assignee of the named inventors. Pharmatop has been, and continues to be, the sole assignee of the '222 patent.

15. Pharmatop granted an exclusive license to the '222 patent to Bristol-Myers Squibb Company ("BMS"), with a right to sublicense. BMS in turn granted Cadence an exclusive sublicense, exclusive even to itself, to the '222 patent with regard to all rights pertinent hereto. A true and correct copy of the '222 patent is attached as Exhibit A.

16. United States Patent No. 6,992,218 ("the '218 patent"), titled "Method for Obtaining Aqueous Formulations of Oxidation-Sensitive Active Principles," was duly and legally issued by the PTO on January 31, 2006, to Pharmatop, the assignee of the named inventors. Pharmatop has been, and continues to be, the sole assignee of the '218 patent.

17. Pharmatop granted an exclusive license to the '218 patent to BMS, with a right to sublicense. BMS in turn granted Cadence an exclusive sublicense, exclusive even to itself, to the '218 patent with regard to all rights pertinent hereto. A true and correct copy of the

'218 patent is attached as Exhibit B.

OFIRMEV®

18. Cadence holds approved New Drug Application (“NDA”) No. 022450 for OFIRMEV®, the first and only intravenous (IV) formulation of acetaminophen available in the United States. OFIRMEV® was approved by the Food and Drug Administration (the “FDA”) on November 2, 2010. OFIRMEV® is indicated for the treatment of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever.

19. The publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '222 patent and the '218 patent were listed in the Orange Book with respect to OFIRMEV®.

THE PADDOCK DEFENDANTS' INFRINGEMENT OF THE PATENTS-IN-SUIT

20. Upon information and belief, Paddock submitted Abbreviated New Drug Application (“ANDA”) No. 202605 to the FDA, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of Acetaminophen Injection, 10 mg/mL, 100 mL vials (“Paddock’s Generic Product”), as a generic version of the OFIRMEV® product, prior to the expiration of the Patents-in-Suit.

21. By a letter dated July 7, 2011 (the “Paddock Letter”), Paddock stated that it had submitted ANDA No. 202605 seeking approval to engage in the commercial manufacture,

use, sale or offer for sale, and/or importation of Paddock's Generic Product prior to the expiration of the Patents-in-Suit.

22. The Paddock Letter also stated that ANDA No. 202605 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that alleges the '222 patent and '218 patent are invalid and that Paddock's Generic Product will not infringe any of the claims of the '218 patent. The Paddock Letter does not state that Paddock's Generic Product will not infringe any of the claims of the '222 patent.

23. Cadence received notice of ANDA No. 202605 and its section 355(j)(2)(A)(vii)(IV) allegations on or about July 8, 2011. However, neither Pharmatop nor Pharmatop's representative have received notice from Paddock as required under 21 USC § 355(j)(2)(B)(iii) and 21 CFR 314.52(a).

24. By filing ANDA No. 202605, Paddock has necessarily represented to the FDA that the components of Paddock's Generic Product have the same active ingredient as that of the corresponding components of OFIRMEV[®], have the same route of administration, dosage form, and strengths as the corresponding components of OFIRMEV[®], and are bioequivalent to the corresponding components of OFIRMEV[®].

25. Paddock's submission of ANDA No. 202605 to the FDA, including the section 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the Patents-in-Suit under 35 USC § 271(e)(2)(A). Moreover, in the event that the Paddock Defendants commercially manufacture, import, use, offer for sale, or sell Paddock's Generic Product or induce or contribute to such conduct, said actions would constitute infringement of the Patents-in-Suit under 35 USC § 271(a), (b) and/or (c).

26. Perrigo is jointly and severally liable for infringement of the Patents-in-Suit. Upon information and belief, Perrigo participated in, contributed to, aided, abetted and/or induced Paddock's submission of ANDA No. 202605 and its section 355(j)(2)(A)(vii)(IV) allegations to the FDA.

27. Upon information and belief, Perrigo has acquired substantially all of Paddock's assets, and as a result of the acquisition by Perrigo, Perrigo is jointly and severally liable for the infringement of the Patents-in-Suit.

28. The Paddock Defendants were aware of the Patents-in-Suit prior to filing ANDA No. 202605, and its actions render this an exceptional case under 35 U.S.C. § 285.

29. The acts of infringement by the Paddock Defendants set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

COUNT I
(Infringement of the '222 Patent)

30. Plaintiffs incorporate each of the preceding paragraphs 1 to 29 as if fully set forth herein.

31. Paddock's submission of ANDA No. 202605, including its § 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '222 patent pursuant to 35 U.S.C. § 271(e)(2) by the Paddock Defendants.

32. Upon FDA approval of ANDA No. 202605, the Paddock Defendants will infringe the '222 patent by making, using, offering to sell, or selling Paddock's Generic Product in the United States and/or importing Paddock's Generic Product into the United

States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b) and/or (c).

33. Upon information and belief, the Paddock Defendants had actual and constructive knowledge of the '222 patent prior to filing ANDA No. 202605 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '222 patent.

COUNT II
(Declaratory Judgment of Infringement of the '222 Patent)

34. Plaintiffs incorporate each of the preceding paragraphs 1 to 33 as if fully set forth herein.

35. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

36. Plaintiffs are further entitled to a declaration that, if the Paddock Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Paddock's Generic Product within the United States, import Paddock's Generic Product into the United States, or induce or contribute to such conduct, the Paddock Defendants would infringe the '222 patent under 35 U.S.C. § 271(a), (b) and/or (c).

37. Plaintiffs will be irreparably harmed by the Paddock Defendants infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT III
(Infringement of the '218 Patent)

38. Plaintiffs incorporate each of the preceding paragraphs 1 to 37 as if fully

set forth herein.

39. Paddock's submission of ANDA No. 202605, including the section 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '218 patent pursuant to 35 U.S.C. § 271(e)(2) by the Paddock Defendants.

40. Upon FDA approval of ANDA No. 202605, the Paddock Defendants will infringe the '218 patent by making, using, offering to sell, or selling Paddock's Generic Product in the United States and/or importing Paddock's Generic Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b) and/or (c).

41. Upon information and belief, the Paddock Defendants had actual and constructive knowledge of the '218 patent prior to filing ANDA No. 202605 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '218 patent.

COUNT IV
(Declaratory Judgment of Infringement of the '218 Patent)

42. Plaintiffs incorporate each of the preceding paragraphs 1 to 41 as if fully set forth herein.

43. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

44. Plaintiffs are further entitled to a declaration that, if the Paddock Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Paddock's Generic Product within the United States, import Paddock's Generic Product into the United

States, or induce or contribute to such conduct, the Paddock Defendants would infringe the '218 patent under 35 U.S.C. § 271(a), (b) and/or (c).

45. Plaintiffs will be irreparably harmed by the Paddock Defendants infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

- A. A judgment that the Paddock Defendants have infringed each of the Patents-In-Suit;
- B. An order issued pursuant to 35 U.S.C. § 271(e)(4)(a) that the effective date of any approval of the Paddock Defendants' ANDA No. 202605 shall not be earlier than the expiration dates of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;
- C. A preliminary and permanent injunction restraining and enjoining the Paddock Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States of the Paddock Defendants' Generic Product until the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;
- D. That Plaintiffs be awarded monetary relief if the Paddock Defendants commercially manufacture, use, offer for sale, or sell their generic version of Cadence's OFIRMEV® brand product, or any other product that infringes or induces or contributes to

the infringement of the Patents-in-Suit, within the United States before the latest expiration date of any of the Patents-In-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

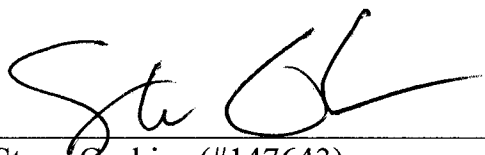
E. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: August 19, 2011

GASKINS BENNETT BIRRELL SCHUPP,
LLP

A handwritten signature in black ink, appearing to read "Steve Gaskins", is written over a horizontal line.

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